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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,828	02/12/2004	Henrik Clausen	20406/1202533-US	5885

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EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,828	CLAUSEN ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/831,630.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-04,2-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 38-41 are currently pending in this application.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/831630, filed on 5-10-01. ***Drawings***

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Specification

Examiner notes that applicants have not updated the relationship of the instant application to its parent application that has matured in to a US patent. Examiner urges applicants to amend said information by providing the US patent number in response to this Office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 38-41 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The applicant has not asserted at least one utility for the claimed isolated polynucleotides. Other than the polynucleotide sequence, SEQ ID NO:8, the specification provides little

functional characterization of this polynucleotide. The specification lists the use for the polynucleotide SEQ ID NO:8 as "that which encodes a polypeptide having UDP-galactose:β-N-acetylglucosamine β 1,3 galactosyltransferase (β3gal-T5) activity", however, there is no information that links the use of the polypeptide encoded by SEQ ID NO:8 to that claimed in the instant claims. Thus the asserted utility of the claimed polynucleotides and its complement sequence is not substantial or specific. Further, while the claims disclose the claimed polynucleotide as "probes", that is not a utility specific to the claimed polynucleotide sequence since the claim does not make it clear as to what or which polynucleotide can be probed using the claimed polynucleotide.

Claims 38-41 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention (see the following rejection below).

Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide of less than 10,000 nucleotides wherein is

said polynucleotide hybridizes to at least to the coding portion of SEQ ID NO:8 under stringent conditions of claim 1, and wherein said polynucleotides a full length polypeptide having UDP-galactose:β-N-acetylglucosamine β 1,3 galactosyltransferase (β3gal-T5) activity, does not reasonably provide enablement for any such polynucleotide or a complement thereof which simply hybridizes to any 20 contiguous nucleotides of nucleotides 1-115 of SEQ ID NO:8 or nucleotides 428-1011 of SEQ ID NO:8 under stringent conditions of claim 1 and exhibits no encoding activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 38-41 are so broad as to encompass any polynucleotide or a complement thereof, which simply hybridizes to any 20 contiguous nucleotides of nucleotides 1-115 of SEQ ID NO:8 or nucleotides 428-1011 of SEQ ID NO:8 under stringent conditions of claim 1 and exhibits no encoding activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a given polynucleotide determines its structural and functional properties, predictability of which

changes can be tolerated in said encoded protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. Simply put, above claims encompass variants of polynucleotide SEQ ID NO:8 which have no function of encoding a functional polypeptide and applicants have not taught those skilled in the art as to where exactly on the polynucleotide sequence of SEQ ID NO:8 specific nucleotides can be modified (i.e., by insertion, deletion or substitution), and how to select those modified sequences that show any utility (i.e., encoding a functional polypeptide). Furthermore, it would also require undue experimentation by those skilled in the art to use polynucleotides without knowing as to what polypeptide it encodes. Therefore it would be an undue burden to those skilled in the art to use the claimed polynucleotide without knowing how to use the encoded polypeptide whose activity applicants have not disclosed in the claim. The specification is limited to teaching the use of the polynucleotide with SEQ ID NO:8 to encode the polypeptide having UDP-galactose:β-N-acetylglucosamine β 1,3 galactosyltransferase (β3gal-T5) activity and use it as a specific glycosyltransferase but provides no guidance with regard to the making of variants and mutants or with regard to the other uses indicated above. In view of the great breadth of the claim, amount of experimentation required to make and use the claimed polynucleotides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue

experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications or multiple uses, as encompassed by the instant claims, and the positions within a polynucleotide sequence leading to variants or mutants through which amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any encoded protein, and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any polynucleotide or a complement thereof which simply hybridizes to any 20 contiguous nucleotides of nucleotides 1-115 of SEQ ID NO:8 or nucleotides 428-1011 of SEQ ID NO:8 under stringent conditions of claim 1 and exhibits no encoding activity because the specification does not establish: (A) regions of the polynucleotide structure which may be modified without affecting its activity of encoding the polypeptide having the specific glycosyltransferase activity; (B) the general tolerance of polynucleotides encoding such glycosyltransferases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleotide on the polynucleotide with an expectation of obtaining the desired biological function; (D) specific uses for polypeptides encoded by the claimed polynucleotides and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful .

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides with an enormous number of nucleotide modifications to SEQ ID NOS: 8 and the broad type of uses for the encoded polypeptides. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 38-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules with either SEQ ID NO:8 or DNA having the limitations of simply hybridizing to nucleotide 1-115 or nucleotides 428-1011 of SEQ ID NO:8 under the stringent conditions described in claim 1.

The specification does not contain any disclosure of the function of all DNA sequences that simply hybridize to nucleotide 1-115 or nucleotides 428-1011 of SEQ ID NO:8 under the stringent conditions described in claim 1. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims,

including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38, 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Szulzewsky et al. (GenBank Accession No. AJ003597, 4 Dec 1997). This rejection is based upon the public availability of a printed publication for more than one year prior to the date of application for patent in the United States. Claims 38, 39 and 41 of the instant application are drawn to an isolated polynucleotide or a complement thereof, which simply hybridizes to any 20 contiguous nucleotides of nucleotides 1-115 of SEQ ID NO:8 under stringent conditions of claim 1 and

exhibits no encoding activity. Szulzewsky et al. discloses such a polynucleotide which has more than 90% sequence identity in the region of nucleotides 93-115 and is therefore capable of hybridizing to nucleotides 1-115 of SEQ ID NO:8. Thus Szulzewsky et al. anticipate claims 38, 39, 41 of this application as written.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,800,468. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 38-41 of the instant application and claims 1-10 of

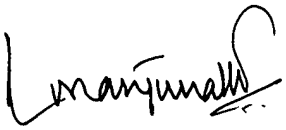
the reference patent are both directed to polynucleotides capable of hybridizing with nucleotides 1-115 and 428-1011 of SEQ ID NO:8. Among all the different polynucleotides claimed in the instant application and in the reference patent a good number of them are identical to one another. The portion of the specification (and the claims) in the reference patent that supports the recited polynucleotides includes several embodiments that would anticipate the polynucleotides claimed in claims 38-41 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims 1-10 of the reference patent when there is specifically recited embodiment that would anticipate mainly claims 38-41 of the instant application. Alternatively, claims 38-41 cannot be considered patentably distinct over claims 1-10 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1-10 of that patent and falls within the scope of claims 38-41 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-10 of the reference by selecting a specifically disclosed embodiment that supports those claims. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-10 of the reference patent.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura

Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

May 25, 2006